



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/872,446	06/10/97	MACEVICZ	S 5525-0015.20

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18M2/1212

EXAMINER
WHISENANT, E

ART UNIT	PAPER NUMBER
1807	4

DATE MAILED:

12/12/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/872,446

Applicant(s)
Macevicz, S.

Examiner
Ethan Whisenant

Group Art Unit
1807



☒ Responsive to communication(s) filed on 10 Jun 1997

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 14 and 15 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 14 and 15 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Part III DETAILED ACTION

SPECIFICATION

- 1.** This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

CLAIM REJECTIONS - 35 USC § 112

- 2.** Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification lacks an adequate written description teaching how to make an oligonucleotide wherein the 5' most bridging O atom of an internucleotide linkage is replaced by a N atom. See the attached diagram showing the examiner's interpretation of one possible embodiment of the claimed invention. Note the N atom in the first (i.e. I) internucleotide linkage. Does this diagram accurately reflect the applicant

- 3.** Claims 18-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is confusing because the phrase "the sum of j and k is less than or equal to 12" is in conflict with the ranges recited for j and k. "j" is said to be 1 to 12 nucleotides while "k" is be 1 to 12 nucleotides. If j is 1 and k is 12 the sum will be 13. Clarification is required. It appears that this portion of the 112, 2nd paragraph rejection can be overcome by changing the range of k to 0 to 11 nucleotides in Claim 18. Likewise Claim 19 suffers from the same discrepancy as regards the sum of s and w.

Claim 19 is indefinite because the letters "j" and "k" lack proper antecedent basis in Claim 19. It appears that "j" and "k" in Claim 19 should be "s" and "w".

Claims 18-19 are unclear because of the phrase "a labeled chain terminating moiety". It is unclear what the applicant intends. Does "a labeled chain terminating moiety" limit the claim by requiring that a moiety, such a dideoxyribonucleotide, be present at the end of the oligonucleotide chain or does a regular nucleotide at the end of an oligonucleotide chain constitute a chain terminating moiety? Clarification is required.

CLAIM REJECTIONS - 35 USC § 102/103

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 19 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Duck et al. [US Patent 5,011,769(1991)].

Claim 19 is drawn to an oligonucleotide probe which is selected from a defined group which includes an oligonucleotide having the following structure: $\text{HO-(3')}(B)_s\text{RRRR}(B)_wB_i^*$; wherein B is a deoxyribonucleotide or an analog thereof; R is a ribonucleotide; s is in the range of from 1 to 8; w is in the range of from 0 to 8, such that the sum of s and w is less than or equal to 8; and B_i^* is a labeled chain terminating moiety. Duck et al. teach such an oligonucleotide. Specifically, Duck et al. teach oligonucleotide probes with a sessile linkage comprising mixed deoxribo- and ribo-oligonucleotides. In addition, Duck et al. teach that one or more of the chain terminating deoxyribonucleotides may be labeled. Finally, Duck et al. teach that the sessile linkage may be a single bond or a multiple unit sequence such as an RNA sequence. See Duck et al., Columns 4-6 and 11-13. The preceding rejection is based on judicial precedent following *In re Fitzgerald*, 205 USPQ 594 because Duck et al. is silent as regards the exact number of ribonucleotides that are to be present in the "middle" of the oligonucleotide probe. In addition, Duck et al. is silent as regards the exact number of deoxyribonucleotides which are to be present "at the ends" of the oligonucleotide probe. Duck et al. does teach in Column 11-12 oligos comprising four ribonucleotides flanked by deoxyribonucleotide sequence. In the examiner's opinion, Duck et al. envisioned oligonucleotide probes having the structure: $\text{HO-(3')}(B)_s\text{RRRR}(B)_wB_i^*$ as being useful in their method. The burden is on the applicant to show that the claimed oligonucleotide is either different or nonobvious

Serial Number: 08/872,446
Art Unit: 1807

4

over those taught by Duck et al. In the examiner's opinion, Duck et al. envisioned and identified oligonucleotide probes having the structure: $\text{HO-(3')}(B)_s\text{RRRR}(B)_wB_t^*$ as being useful in their method.

6. Claims 18 would appear to be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action. Claim 18 appears to be allowable over the prior art because of the unique internucleotide linkage comprising a N atom in place of a 5' most bridging O atom in an internucleotide linkage. The examiner is unaware of a reference that teaches such a construct. The closest prior art discovered against this claim is Beaton et al. [US Patent no. 5,525,050 (1997)]. Beaton et al. teach oligos wherein the 5' most bridging O atom in an internucleotide linkage is replaced by a C atom.

CONCLUSION

7. No claims are allowed. The closest art discovered during the search was that disclosed on the attached PTO-892.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:00AM -4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Group is (703) 305-7401. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.

ECW

Ethan Whisenant, Ph.D.
Patent Examiner

[Signature]
W. GARY JONES
SUPERVISORY PATENT EXAMINER
GROUP 1800

12/879